

AMENDED IN ASSEMBLY MAY 28, 2015
AMENDED IN ASSEMBLY APRIL 30, 2015
AMENDED IN ASSEMBLY APRIL 21, 2015
AMENDED IN ASSEMBLY MARCH 25, 2015
AMENDED IN ASSEMBLY MARCH 11, 2015
CALIFORNIA LEGISLATURE—2015–16 REGULAR SESSION

ASSEMBLY BILL

No. 170

Introduced by Assembly Member Gatto

January 22, 2015

An act to amend Section 125000 of, and to add Sections ~~125003 and 125004~~ 125003, 125004, and 125005 to, the Health and Safety Code, relating to newborn screening.

LEGISLATIVE COUNSEL'S DIGEST

AB 170, as amended, Gatto. Newborn screening: genetic diseases: blood samples collected.

Existing law requires the State Department of Public Health to establish a program for the development, provision, and evaluation of genetic disease testing, and the program is required to provide genetic screening and followup services for persons who have the screening. The program includes statewide screening of newborn children through the collection of blood samples, unless the parent or guardian objects on the grounds of religious beliefs or practices.

This bill would require the department to provide information about the testing program, and to obtain a form signed by the parent or guardian acknowledging receiving information regarding the storage,

retention, and use of the newborn child's blood sample for medical research. The bill would authorize a parent or guardian of a minor child, and the newborn child, once he or she is at least 18 years of age, to request that the department destroy the blood sample, not use it for research purposes, or both, and the bill would require the department to comply with the request. The bill would also require the department to prepare and provide informational materials regarding the same information about the newborn child's blood sample collected pursuant to the program, information on storage, retention, and use of the blood sample for medical research, and the right of specified persons to request that the blood sample be destroyed or not used for research purposes in a separate, single-page format. The bill would also require the department to prepare and provide a standard informational acceptance form, that includes, among other things, a brief, plain language explanation of, and the purpose for, the newborn child screening test and retention of newborn child blood samples. The bill would require the informational acceptance form to be provided to, and signed by, the parent or guardian when either version of the informational materials is provided. The bill would require specified persons to distribute the informational material and the informational acceptance form, including requiring the local registrar of births to provide a copy of the informational material and a copy of the standard informational acceptance form to each person registering the birth of a newborn that occurred outside of a perinatal licensed health facility, as specified. The bill would also require the local registrar to notify the local health officer and the department of each of these registrations by the local registrar. By imposing additional duties on local registrars of births, this bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that, if the Commission on State Mandates determines that the bill contains costs mandated by the state, reimbursement for those costs shall be made pursuant to these statutory provisions.

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: yes.

The people of the State of California do enact as follows:

1 SECTION 1. Section 125000 of the Health and Safety Code
2 is amended to read:

3 125000. (a) (1) It is the policy of the State of California to
4 make every effort to detect, as early as possible, phenylketonuria
5 and other preventable heritable or congenital disorders leading to
6 intellectual disability or physical defects.

7 (2) The department shall establish a genetic disease unit, that
8 shall coordinate all programs of the department in the area of
9 genetic disease. The unit shall promote a statewide program of
10 information, testing, and counseling services and shall have the
11 responsibility of designating tests and regulations to be used in
12 executing this program.

13 (3) The information, tests, and counseling for children shall be
14 in accordance with accepted medical practices and shall be
15 administered to each child born in California. The department shall
16 provide information about the tests and shall obtain a signed
17 informational acknowledgment form for the receipt of information
18 by the parent or guardian of a newborn child regarding the storage,
19 retention, and use of the newborn child's blood sample for medical
20 research. The department shall establish appropriate regulations
21 and testing methods. The information, tests, and counseling for
22 pregnant women shall be in accordance with accepted medical
23 practices and shall be offered to each pregnant woman in California
24 once the department has established appropriate regulations and
25 testing methods. These regulations shall follow the standards and
26 principles specified in Section 124980. The department may
27 provide laboratory testing facilities or contract with any laboratory
28 that it deems qualified to conduct tests required under this section.
29 However, notwithstanding former Section 125005, provision of
30 laboratory testing facilities by the department shall be contingent
31 upon the provision of funding therefor by specific appropriation
32 to the Genetic Disease Testing Fund enacted by the Legislature.
33 If moneys appropriated for purposes of this section are not
34 authorized for expenditure to provide laboratory facilities, the
35 department may nevertheless contract to provide laboratory testing
36 services pursuant to this section and shall perform laboratory
37 services, including, but not limited to, quality control, confirmatory,

1 and emergency testing, necessary to ensure the objectives of this
2 program.

3 (b) The department shall charge a fee for any tests performed
4 pursuant to this section. The amount of the fee shall be established
5 and periodically adjusted by the director in order to meet the
6 reasonable costs of this section.

7 (c) The department shall inform all hospitals or physicians and
8 surgeons, or both, of required regulations and tests and may alter
9 or withdraw any of these requirements whenever sound medical
10 practice so indicates. To the extent practicable, the department
11 shall provide notice to hospitals and other payers in advance of an
12 increase in the fees charged for the program.

13 (d) This section shall not apply if a parent or guardian of a
14 newborn child objects to a test on the ground that the test conflicts
15 with his or her religious beliefs or practices.

16 (e) The genetic disease unit is authorized to make grants or
17 contracts or payments to vendors approved by the department for
18 all of the following:

19 (1) Testing and counseling services.

20 (2) Demonstration projects to determine the desirability and
21 feasibility of additional tests or new genetic services.

22 (3) To initiate the development of genetic services in areas of
23 need.

24 (4) To purchase or provide genetic services from any sums as
25 are appropriated for this purpose.

26 (f) (1) The genetic disease unit shall evaluate and prepare
27 recommendations on the implementation of tests for the detection
28 of hereditary and congenital diseases, including, but not limited
29 to, biotinidase deficiency and cystic fibrosis. The genetic disease
30 unit shall also evaluate and prepare recommendations on the
31 availability and effectiveness of preventative followup
32 interventions, including the use of specialized medically necessary
33 dietary products.

34 (2) It is the intent of the Legislature that funds for the support
35 of the evaluations and recommendations required pursuant to this
36 subdivision, and for the activities authorized pursuant to
37 subdivision (e), shall be provided in the annual Budget Act
38 appropriation from the Genetic Disease Testing Fund.

39 (g) Health care providers that contract with a prepaid group
40 practice health care service plan that annually has at least 20,000

1 births among its membership, may provide, without contracting
2 with the department, any or all of the testing and counseling
3 services required to be provided under this section or the
4 regulations adopted pursuant thereto, if the services meet the
5 quality standards and adhere to the regulations established by the
6 department, the plan pays that portion of a fee established under
7 this section that is directly attributable to the department's
8 reasonable cost of administering the testing or counseling service
9 and attributable to any required testing or counseling services
10 provided by the state for plan members. The payment by the plan,
11 as provided in this subdivision, shall be deemed to fulfill any
12 obligation the provider or the provider's patient may have to the
13 department to pay a fee in connection with the testing or counseling
14 service.

15 (h) The department may appoint experts in the area of genetic
16 screening, including, but not limited to, cytogenetics, molecular
17 biology, prenatal, specimen collection, and ultrasound, to provide
18 expert advice and opinion on the interpretation and enforcement
19 of regulations adopted pursuant to this section. These experts shall
20 be designated agents of the state with respect to their assignments.
21 These experts shall not receive a salary, but shall be reimbursed
22 for expenses associated with the purposes of this section. All
23 expenses of the experts for the purposes of this section shall be
24 paid from the Genetic Disease Testing Fund.

25 (i) A parent or legal guardian of a minor may request the
26 department destroy the blood sample of the minor collected as a
27 newborn, or not use it for research purposes, or both, and the
28 department shall comply with that request.

29 (j) An individual who is at least 18 years of age may request
30 the department destroy his or her blood sample that was collected
31 as a newborn, or not use it for research purposes, or both, and the
32 department shall comply with that request.

33 SEC. 2. Section 125003 is added to the Health and Safety Code,
34 to read:

35 125003. (a) The department shall prepare and provide
36 informational materials regarding newborn child blood samples
37 collected pursuant to this article that include, but are not limited
38 to, all of the following:

39 ~~(1) Storage, retention, and use of the blood sample.~~

1 ~~(2) The parent or legal guardian's right to request that his or her~~
2 ~~minor child's blood sample be destroyed or not used for research~~
3 ~~purposes, or both, and the information necessary to make that~~
4 ~~request.~~

5 ~~(3) The right of an individual who is at least 18 years of age to~~
6 ~~request that his or her blood sample be destroyed or not used for~~
7 ~~research purposes, or both, and the information necessary to make~~
8 ~~that request.~~

9 ~~(b) These informational materials shall be confined to a single~~
10 ~~page and presented in a separate document from informational~~
11 ~~materials pertaining to the newborn screening program.~~

12 ~~(c) The department shall provide to a parent or legal guardian~~
13 ~~the standard informational acceptance form provided in Section~~
14 ~~125004 regarding the retention of newborn child blood samples~~
15 ~~collected pursuant to this article.~~

16 ~~(d) The informational materials and the standard informational~~
17 ~~acceptance form prepared and provided by the department shall~~
18 ~~be distributed as follows:~~

19 ~~(1) Every birth attendant engaged in providing perinatal care~~
20 ~~shall provide a pregnant woman, prior to the estimated date of~~
21 ~~delivery, with a copy of the informational materials and a copy of~~
22 ~~the standard informational acceptance form provided by the~~
23 ~~department.~~

24 ~~(2) Every perinatal licensed health facility shall provide each~~
25 ~~pregnant woman admitted for delivery with a copy of the~~
26 ~~informational materials and a copy of the standard informational~~
27 ~~acceptance form provided by the department, prior to collection~~
28 ~~of the blood sample, if that information or standard informational~~
29 ~~acceptance form has not been provided pursuant to paragraph (1).~~

30 ~~(3) The local registrar of births shall provide a copy of the~~
31 ~~informational material and a copy of the standard informational~~
32 ~~acceptance form provided by the department to each person~~
33 ~~registering the birth of a newborn that occurred outside of a~~
34 ~~perinatal licensed health facility when the newborn was not~~
35 ~~admitted to a perinatal licensed health facility within the first 30~~
36 ~~days of age. The local health officer and the department shall be~~
37 ~~notified of each of these registrations by the local registrar.~~

38 ~~(e) For the purposes of this section, the following terms shall~~
39 ~~have the following meanings:~~

1 (1) ~~“Birth attendant” means a person licensed or certified by~~
2 ~~the state to provide maternity care and to deliver pregnant women~~
3 ~~or to practice medicine.~~

4 (2) ~~“Perinatal licensed health facility” means a health facility~~
5 ~~licensed by the state and approved to provide perinatal, delivery,~~
6 ~~newborn intensive care, newborn nursery, or pediatric services.~~

7 (1) *A brief, plain language explanation of, and the purpose for,*
8 *the newborn child screening test and the storage, retention, and*
9 *use of newborn child blood samples collected pursuant to this*
10 *article.*

11 (2) *A description of the benefits of both early newborn child*
12 *screening and the associated research undertaken regarding*
13 *preventable heritable or congenital disorders.*

14 (3) *A description of the California Biobank Program,*
15 *specifically as it pertains to the Genetic Disease Screening*
16 *Program, and subsequent storage, retention, and use of the*
17 *newborn child’s blood sample for medical research.*

18 (4) *An explanation of the parent’s or legal guardian’s right to*
19 *request that his or her minor child’s blood sample be destroyed*
20 *or not used for research purposes, or both, and the information*
21 *necessary to make that request.*

22 (5) *A statement that an individual who is at least 18 years of*
23 *age has the right to request that his or her blood sample be*
24 *destroyed or not used for research purposes, or both, and the*
25 *information necessary to make that request.*

26 (b) *These informational materials shall be confined to a single*
27 *page and presented in a separate document from the standard*
28 *informational acceptance form required in Section 125004.*

29 SEC. 3. Section 125004 is added to the Health and Safety Code,
30 to read:

31 125004. (a) The department shall prepare a standard
32 informational acceptance form that includes all of the following:

33 (1) A brief, plain language explanation of, and the purpose for,
34 the newborn child screening test and retention of newborn child
35 blood samples collected pursuant to this article.

36 (2) ~~A description of the benefits of both early newborn child~~
37 ~~screening and the associated research undertaken regarding~~
38 ~~preventable heritable or congenital disorders.~~

39 (3) ~~A description of the California Biobank Program, specifically~~
40 ~~as it pertains to the Genetic Disease Screening Program, and~~

1 subsequent storage, retention, and use of the newborn child’s blood
 2 sample for medical research.

3 ~~(4) A space for the parent or legal guardian of the newborn child
 4 to acknowledge receipt of informational materials regarding the
 5 storage, retention, and use of the newborn child’s blood sample
 6 for medical research.~~

7 ~~(5) (a) A space for the parent or legal guardian of the newborn
 8 child to sign and date the form.~~

9 ~~(b) A copy of the standard informational acceptance form shall
 10 be maintained with the medical records of the mother of the
 11 newborn child.~~

12 ~~(c) As used in this article, “informational acceptance form”
 13 means a written acknowledgment of received informational
 14 materials, signed and dated by a parent or legal guardian of a
 15 newborn child.~~

16 ~~(d) If there is no signed standard informational acceptance form
 17 retained in the mother’s medical record, the newborn child shall
 18 still be administered the genetic screening test and the newborn
 19 child blood sample shall be stored and retained for medical research
 20 pursuant to Section 125000.~~

21 *(2) An explanation of the parent’s or legal guardian’s right to
 22 request that his or her minor child’s blood sample be destroyed
 23 or not used for research purposes, or both, and the information
 24 necessary to make that request.*

25 *(3) A space for the parent or legal guardian of the newborn
 26 child to acknowledge receipt of informational materials regarding
 27 the storage, retention, and use of the newborn child’s blood sample
 28 for medical research.*

29 *(4) A space for the parent or legal guardian of the newborn
 30 child to sign and date the form.*

31 *(b) The standard informational acceptance form shall be
 32 confined to a single page and presented in a separate document
 33 from the informational materials required in Section 125003.*

34 *(c) A copy of the standard informational acceptance form shall
 35 be maintained in the medical record of the mother of the newborn
 36 child.*

37 *(d) As used in this article, “informational acceptance form”
 38 means a written acknowledgment of received informational
 39 materials, signed and dated by a parent or legal guardian of a
 40 newborn child.*

1 (e) *In the event that there is no signed standard informational*
2 *acceptance form retained in the mother's medical record, the*
3 *newborn child shall be administered the genetic screening test and*
4 *the newborn child blood sample shall be stored and retained for*
5 *medical research pursuant to Section 125000.*

6 SEC. 4. *Section 125005 is added to the Health and Safety Code,*
7 *to read:*

8 125005. (a) *The department shall provide a parent or legal*
9 *guardian with the informational materials described in Section*
10 *125003 and the standard informational acceptance form described*
11 *in Section 125004 regarding the retention of newborn child blood*
12 *samples collected pursuant to this article.*

13 (b) *The informational materials and standard informational*
14 *acceptance form described in Section 125004 shall be distributed*
15 *as follows:*

16 (1) *A birth attendant engaged in providing perinatal care shall*
17 *provide a pregnant woman, prior to the estimated date of delivery,*
18 *with a copy of the informational materials and a copy of the*
19 *standard informational acceptance form provided by the*
20 *department.*

21 (2) *If the informational materials or standard informational*
22 *acceptance form has not been provided pursuant to paragraph*
23 *(1), a perinatal licensed health facility shall provide each pregnant*
24 *woman admitted for delivery with a copy of the informational*
25 *materials and a copy of the standard informational acceptance*
26 *form provided by the department.*

27 (3) *The local registrar of births and deaths shall provide a copy*
28 *of the informational material and a copy of the standard*
29 *informational acceptance form provided by the department to each*
30 *person registering the birth of a newborn that occurred outside*
31 *of a perinatal licensed health facility when the newborn was not*
32 *admitted to a perinatal licensed health facility within the first 30*
33 *days of age. The local registrar of births and deaths shall notify*
34 *the local health officer and the department of each of these*
35 *registrations.*

36 (c) *For the purposes of this section, the following terms shall*
37 *have the following meanings:*

38 (1) *"Birth attendant" means a person licensed or certified by*
39 *the state to provide maternity care and to deliver pregnant women*
40 *or to practice medicine.*

1 (2) *“Perinatal licensed health facility” means a health facility*
2 *licensed by the state and approved to provide perinatal, delivery,*
3 *newborn intensive care, newborn nursery, or pediatric services.*

4 ~~SEC. 4.~~

5 SEC. 5. If the Commission on State Mandates determines that
6 this act contains costs mandated by the state, reimbursement to
7 local agencies and school districts for those costs shall be made
8 pursuant to Part 7 (commencing with Section 17500) of Division
9 4 of Title 2 of the Government Code.